

### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

March 11, 2015

Ms. Miriam Frugis
Bayer CropScience LP
P.O. Box 12014
2 T.W. Alexander Drive
Research Triangle Park, NC 27709

Subject: Label Amendment – Adding clarifying statement to rotation crop restriction -In case of crop failure due to an early season catastrophic event, soybean see (treated or un-treated) can be immediately replanted.

Product Name: Fluopyram ST

EPA Registration Number: 264-1167 Application Date: February 20, 2015 Decision Number: February 23, 2015

#### Dear Ms. Frugis:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or

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misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Tamue L. Gibson by phone at (703) 305-9096, or via email at gibson.tamue@epa.gov.

Sincerely,

Shaja B. Joyner, Product Manager 20

Fungicide Herbicide Branch Registration Division (7505P) Office of Pesticide Programs

Enclosure:

Main Product Label Stamped "Accepted"

GROUP 7 FUNGICIDE

### Fluopyram ST

### **ABN: ILeVO®**

A systemic seed treatment for use on cotton and soybean for the protection against damage caused by early season plant pathogenic nematodes. As a soybean seed treatment provides protection from seedling infections by *Fusarium virguliforme*, the causal agent of Sudden Death Syndrome.

#### **ACTIVE INGREDIENT:**

Contains 5 lbs FLUOPYRAM per gallon (600 g FLUOPYRAM per liter)

\*(CAS Number 658066-35-4)

EPA Reg. No. 264-1167

EPA Est. No.

# KEEP OUT OF REACH OF CHILDREN CAUTION

#### **FIRST AID**

#### IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Have person sip a glass of water if able to swallow.
- Do not give anything to an unconscious person.

#### For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577.

In case of emergency call toll free the Bayer CropScience Emergency Response Telephone No. 1-800-334-7577.

Have a product container or label with you when calling a poison control center or doctor, or going for treatment.

**NOTE TO PHYSICIAN:** Treat Symptomatically

For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

ACCEPTED

03/11/2015

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

264-1167

#### PRECAUTIONARY STATEMENTS

## HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

#### **Personal Protective Equipment (PPE):**

Workers involved with treating the seed (e.g. connecting and disconnecting hoses and transfer pumps, mixing, equipment calibration, etc) and other exposed to the concentrate, and cleaners/repairers of seed treatment equipment must wear a long-sleeve shirt and long pants, shoes plus socks, and waterproof (such as natural rubber, barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyethylene, polyvinyl chloride, or viton) gloves (if more options are needed, follow the instructions for category A on an EPA chemical-resistance category selection chart).

Baggers and bag sewers must wear a long-sleeve shirt and long pants, and shoes plus socks.

#### **User Safety Requirements**

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

#### **User Safety Recommendations**

#### Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- User should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

#### **ENVIRONMENTAL HAZARDS**

For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate. This product may impact surface water quality due to runoff of rain water. This is especially true for poorly draining soils and soils with shallow ground water. This product is classified as having high potential for reaching surface water via runoff for several months or more after application. A level, well-maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential loading of FLUOPYRAM. Runoff of this product will be reduced by avoiding applications when rainfall or irrigation is expected to occur within 48 hours. Sound erosion control practices will reduce this product's potential to reach aquatic sediment via runoff.

This chemical has properties and characteristics associated with chemicals detected in ground water. This chemical may leach into groundwater if used in areas where soils are permeable, particularly where the water table is shallow.

Treated seed exposed on soil surface may be hazardous to wildlife. Cover or collect seed spilled during loading

### DIRECTIONS FOR USE STOP - READ THE ENTIRE LABEL BEFORE USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For use only in commercial seed treatment equipment. Not for use in hopper box, planter box, slurry box, or other on-farm seed treatment applications. Read the entire label and observe all label directions and precautions before use. Do not use this product except as directed on this label or on other Bayer CropScience supplemental labeling for this product.

#### PRODUCT INFORMATION

FLUOPYRAM ST is a seed treatment labeled for the control or suppression of certain plant pathogenic fungi and nematodes.

#### **LABELED USES**

Cotton and Soybeans Seeds.

#### **RESISTANCE MANAGEMENT**

The active ingredient in FLUOPYRAM ST belongs to the pyridinyl-ethyl-benzamides (Group 7). Because resistance development cannot be predicted, the use of this product should conform to resistance management strategies established for the crop and use area. Such strategies may include rotating and/or tank mixing with products having different modes of action; or limiting the total number of applications per season. Use labeled rates. Contact your local extension specialist, certified crop advisor, and/or manufacturer for fungicide/insecticide resistance management and/or integrated pest management recommendations for specific crops and pest populations. Bayer CropScience encourages responsible product stewardship to ensure effective long-term control of pests on this label.

#### **ROTATIONAL CROP RESTRICTIONS**

The following crops may be replanted immediately following the last application of Fluopyram ST: cotton, dried beans, peanut, potato, sugar beet, strawberry, and watermelon. Do not replant alfalfa for 14 days after application. Canola may be replanted after 30 days. Cereals (including corn but excluding rice) and soybean may be replanted after 8 months. Do not rotate to crops other than those listed above.

In case of crop failure due to an early season catastrophic event, soybean seed (treated or un-treated) can be immediately replanted.

#### **USE INFORMATION**

FLUOPYRAM ST is a seed treatment that when applied to seed, aids in protecting the seed and seedling against certain early season plant pathogenic fungi and nematodes that attack the root system. In areas of high nematode infestation additional control measures may be warranted. The use of FLUOPYRAM ST can suppress early season infection by *Fusarium virguliforme*, the causal agent of Sudden Death Syndrome.

#### **COMPATIBILITY**

It is essential that before using FLUOPYRAM ST seed treatment in any tank mixture the compatibility of the mixture be established. Add FLUOPYRAM ST at the labeled rate to a clean quart jar containing approximately one-half the amount of water intended for a final slurry application rate. Next, follow with all other tank mix components that will be used in the total slurry application. Add last the remaining balance of water. The total amount of volume is determined by the seed size and how much is necessary to ensure complete and uniform coverage and distribution on the seed, as well as the type of commercial seed treating application equipment that will be used.

DO NOT USE MIXTURES THAT CURDLE, PRECIPITATE, OR GEL. USE TANK MIXTURES IMMEDIATELY AFTER MIXING WITH ADEQUATE AGITATION.

#### **MIXING INSTRUCTIONS**

When applied with seed treatment application equipment designed to treat seed utilizing a treatment slurry mixture, add approximately 1/2 to 2/3 of the required water to the treatment slurry tank followed by the accompanying seed treatment products and FLUOPYRAM ST. The order of product addition is dependent on the accompanying seed treatment products and application equipment used. Allow each slurry component to disperse completely prior to the next addition until a uniform suspension is obtained. After all slurry components have been added and dispersed completely add the remaining 1/2 to 1/3 of required water for proper slurry volume and mix until uniform. Do not store mixed slurries for greater than 72 hours. Maintain adequate agitation until treatment slurry is applied. For additional instructions for use, slurry component mixing order, and other application suggestions contact your Bayer CropScience representative.

#### **APPLICATION RATES**

May be used in combination with other registered Bayer CropScience seed treatment fungicides and insecticides. Pre-test for compatibility with other seed treatment products.

SOYBEAN			
Disease Control	Application Rates <sup>A</sup>	Product Instructions	
Sudden Death Syndrome (Fusarium viguliforme)	0.15 - 0.25 mg ai/seed or 1.18 to 1.97 fl oz (35 to 58 ml) / 140,000 soybean seeds	Apply using commercial slurry or mist-type seed treatment equipment. Uniform application of seed is necessary to ensure seed safety and best disease protection. Dilute product with sufficient water to ensure complete seed coverage. Apply to high quality, properly cleaned seeds.	
Soilborne Nematodes (Heterodera glycines, Meloidogyne incognita, Rotylenchulus reniformis, Pratylenchus spp., Hoplolaimus sp.)	0.075 - 0.25 mg ai/seed or 0.6 to 1.97 fl oz (18 to 58 ml)/ 140,000 soybean seeds	This product does not contain colorant. The purchaser of this product is responsible for ensuring that all seed treated with this product are adequately dyed with a suitable color to prevent its accidental use as food for man or feed for animals. Refer to 21CFR, part 2.25. Any colorant added to treated seed must be cleared for use under 40CFR, part 153.155.	

**Restrictions:** Seeds may not be broadcast planted. Do not apply more than 0.22 lbs of fluopyram per acre per year.

A Do not graze or feed soybean forage and hay to livestock after treating with Fluopyram ST.

COTTON			
Disease Protection	Application Rates	Product Instructions	
Soilborne Nematodes (Meloidogyne incognita, Rotylenchulus reniformis, Hoplolaimus spp.)	0.175 - 0.35 mg ai/seed or 0.985 - 1.97 fl oz (29.13 - 58.26 ml)/ 100,000 cotton seeds	Apply using commercial slurry or mist-type seed treatment equipment. Uniform application of seed is necessary to ensure seed safety and best disease protection. Dilute product with sufficient water to ensure complete seed coverage. Apply to high quality, properly cleaned seeds.  This product does not contain colorant. The purchaser of this product is responsible for ensuring that all seed treated with this product are adequately dyed with a suitable color to prevent its accidental use as food for man or feed for animals. Refer to 21CFR, part 2.25. Any colorant added to treated seed must be cleared for use under 40CFR, part 153.155.	

Restrictions: Seeds may not be broadcast planted.

#### **SEED BAG TAG**

The Federal Seed Act requires that the container of seed treated with FLUOPYRAM ST must be labeled with the following statements:

This seed has been treated with FLUOPYRAM ST, which contains 48.4% of Fluopyram.

Do not use treated seed for food, feed, or oil purposes. Excess treated seed may be used for ethanol production only if (1) by-products are not used for livestock feed and (2) no measurable residues of pesticide remain in ethanol by-products that are used in agronomic practice.

- Store treated seeds away from food and feedstuffs.
- Do not allow children, pets, or livestock to have access to treated seed.
- Wear long-sleeved shirt, long pants and chemical-resistant gloves when handling treated seed.
- Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading.
- Dispose of all excess treated seed. Leftover treated seed may be buried away from water sources in accordance with local requirements.
- Do not contaminate water bodies when disposing of planting equipment wash waters.
- Treated seed must be adequately covered with soil at planting.
- Dispose of seed packaging or containers in accordance with local requirements. Do not use empty seed bags for any other purpose.
- To reduce seed dust which can drift onto blooming crops or weeds, ensure that planting equipment is functioning properly in accordance with manufacturer's recommendations. Surplus seed or empty seed containers should be stored or disposed according to local federal regulations.
- Do not graze or feed soybean forage and hay to livestock after treating with Fluopyram ST.
- Treated at manufacturer's recommended rate

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage, disposal or cleaning of equipment.

#### **PESTICIDE STORAGE**

Store in original container away from feed and food. Store in cool, dry area. Do not store in direct sunlight. Do not allow prolonged storage in temperatures that exceed 105°F (40°C) or in temperatures that fall below 14°F (-10°C).

#### PESTICIDE DISPOSAL

To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

#### **CONTAINER HANDLING**

#### Dilutable Seed Treatment Products in Non-Refillable Plastic Containers

Rigid Non-refillable containers that are too large to shake (i.e., with capacities greater than 5 gallons or 50 lbs)

Non-refillable container. Do not reuse or refill this container. After emptying product from container, either return container to Bayer

CropScience per instructions from Bayer CropScience Customer Service Center (1-800-527-4781), or rinse and either recycle or
dispose of the container as follows:

#### Bottom Discharge IBC (e.g. - Schuetz Caged IBC or Snyder Square Stackable)

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. To pressure rinse the container before final disposal, empty the remaining contents from the IBC into application equipment or mix tank. Raise the bottom of the IBC by 1.5 inches on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into application equipment or rinsate collection system while pressure rinsing. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

#### Top Discharge IBC, Drums, Kegs (e.g.- Snyder 120 Next Gen, Bonar B120, Drums, and Kegs)

Triple rinsing the container before final disposal is the responsibility of the person disposing of the container. To triple rinse the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

#### <u>Dilutable Seed Treatment Products in Non-Refillable Metal Containers</u>

Nonrefillable container. Do not reuse or refill this container. After emptying product from container, either return container to Bayer CropScience per instructions from Bayer CropScience Customer Service Center (1-800-527-4781), or rinse and either recycle or dispose of the container as follows:

#### Liquid dilutables in containers small enough to shake (5 gallons or less)

Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

#### Solid dilutables in containers small enough to shake (5 gallons or 50 pounds or less)

Triple Rinse as follows: Empty the remaining contents into application equipmentor a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

#### Any dilutable pesticides in containers too large to shake (larger than 5 gallons or 50 pounds)

Triple Rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

#### Non-Dilutable Seed-Treatment Products in Non-Refillable Containers

#### Seed-Treatment Products in Non-Refillable Fiber Drums with Liners

Non-refillable container. Do not reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment, then offer for recycling if available or dispose of in a sanitary landfill or by incineration. If drum is contaminated and cannot be reused, dispose of it in the manner required for its liner.

#### Seed-Treatment Products in Non-rigid, Non-Refillable Containers

Nonrefillable container. Do not reuse or refill this container. Completely empty container into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

#### Seed Treatment Products in Refillable Containers

Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. After emptying product from container, either return container to Bayer CropScience per instructions from Bayer CropScience Customer Service Center (1-800-527-4781) or rinse and either recycle or dispose of the container as follows:

#### Bottom Discharge IBC (e.g. - Schuetz Caged IBC or Snyder Square Stackable)

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To pressure rinse the container before final disposal, empty the remaining contents from the IBC into application equipment or mix tank. Raise the bottom of the IBC by 1.5 inches on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into application equipment or rinsate collection system while pressure rinsing. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve. Top Discharge IBC, Drums, Kegs (e.g. – Snyder 120 Next Gen, Bonar B120, Drums, and Kegs)

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Triple rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To triple rinse the containers before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.

End users are authorized to remove tamper evident cables as required to remove the product from the container unless the container is equipped with one way valves and refilling or returning is planned. If this is the case, end users are not authorized to remove tamper evident cables, one way valves or clean container.

#### IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

Treatment of highly mechanically damaged seed, or seed of known low vigor and poor quality, may result in reduced germination and/or reduction of seed and seedling vigor. Treat and conduct germination tests on a small portion of seed before committing the total seed lot to a selected chemical treatment. Due to seed quality conditions beyond the control of Bayer CropScience, no claims are made to guarantee germination of carry-over seed.

**CONDITIONS:** The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE SHALL NOT BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

**LIMITATIONS OF LIABILITY**: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

FLUOPYRAM ST is specially formulated and sold by Bayer CropScience LP for the control of various pathogens according to the directions on this label. The purchase price of FLUOPYRAM ST includes a prepaid license under which purchaser agrees to employ the purchased quantity of FLUOPYRAM ST only for the above-specified uses and to provide notice of the terms and conditions of this license to any subsequent purchaser. Uses of FLUOPYRAM ST other than those specified on this label are not licensed through the purchase of this product.

#### **NET CONTENTS:**

#### PRODUCED FOR



Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, North Carolina 27709 1-866-99BAYER (1-866-992-2937)

Fluopyram ST (PENDING) 02/20/2015